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Home Respiratory Care Review

April 2005

PROBLEM

Since the 1980s, there has been a growing trend towards home care and the home use of sophisticated medical devices by unqualified caregivers. As a result, patient safety and the clinical effectiveness of medical devices, as they pertain to respiratory care, has declined, jeopardizing respiratory patients' health, safety, and welfare. In addition, reports of fraud are prevalent among many home care providers.

BACKGROUND

Patient care provided in the home environment has evolved as significant changes in medical care delivery have occurred over the past few decades. Prior to World War II, medical care was primarily a home affair, with doctors and nurses visiting the patient in the home, and hospital-based care reserved primarily for the severely ill. After World War II, as medical diagnosis and therapy became more sophisticated and intensive, of necessity it was delivered primarily in medical care facilities, such as hospitals, medical offices, and clinics.

However, in the 1980s, the home care movement reemerged for an entirely different purpose and with a whole new set of caregivers. As health care delivery continues to advance and efforts to control healthcare costs continue, more patients are being cared for at home or at other non-clinical places for their convalescence. Home care is now being provided primarily by patients' family members and non-clinical personnel. Many of the patients (ranging from newborns to the elderly) rely on medical devices for treatment or to sustain life. There is a broad range of capabilities and limitations in the population of potential medical device users and their caregivers. Limitations are both cognitive and physical.

The current process whereby decisions about releasing patients from hospitals to home care are frequently made without adequate assessment of the capability of the home caregivers or the suitability of the home environment. Furthermore, home care is going on outside of the control or supervision of regulated agencies.

In 2001, the Respiratory Care Board of California underwent a review by the Joint Legislative Sunset Review Committee and noted its concern for the lack of regulatory oversight for respiratory care provided in the home. In response, recommendations made by the Joint Committee included their support as well as the California Department of Consumer Affairs' support for the Board's effort to review this matter.

In 2002, the U.S. Food and Drug Administration (**FDA**) held two public meetings (June 6th and 7th and September 12th and 13th) to examine the home use of medical devices [**Attachment 1]**. One of the FDA's findings was that there was a general consensus that the use of medical devices in the home should be officially recognized, and that it should not occur simply by default. Manufacturers should acknowledge the possible or probable use of their devices in the home, and the regulatory process should do so as well.

As a result of the growing home care movement, the FDA, home care accrediting agencies, medical device retailers, home health agencies, and many state boards for respiratory care are examining the many faceted issues and problems that have come about in an effort to find resolutions and improve patient safety.

MEDICAL DEVICES

In California, “home medical device” is defined in the Health and Safety Code, section 109948.1, subdivision (b) as "a device intended for use in a home care setting including, but not limited to, all of the following:

(1) Oxygen delivery systems and prefilled cylinders.
(2) Ventilators.
(3) Continuous Positive Airway Pressure devices (CPAP).
(4) Respiratory disease management devices.
(5) Hospital beds and commodes.
(6) Electronic and computer driven wheelchairs and seating systems.
(7) Apnea monitors.
(8) Low air loss continuous pressure management devices.
(9) Transcutaneous Electrical Nerve Stimulator (TENS) units.
(10) Prescription devices.
(11) Disposable medical supplies including, but not limited to, incontinence supplies as defined in Section 14125.1 of the Welfare and Institutions Code. ***[This item is not generally considered a "medical device" and is not included in devices required to be approved by the FDA.]***
(12) In vitro diagnostic tests.
(13) Any other similar device as defined in regulations adopted by the department.

The FDA defines medical device as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

* recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
* intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
* intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of it's primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."

All medical devices must be approved by or meet performance standards set by the FDA. The Federal Food, Drug, and Cosmetic Act of 1938 extended the FDA's control among other things, to therapeutic devices. In 1976, medical device amendments passed to ensure safety and effectiveness of medical devices, including diagnostic products. These amendments required manufacturers to register with FDA and follow quality control procedures.

The FDA's approval of medical devices has been done so with the expectation that the devices would be used by trained health care practitioners in controlled health care delivery facilities. Thus sophisticated medical devices are being used under conditions that neither their manufacturers nor the regulatory system had necessarily contemplated or intended.

Some medical devices such as wheelchairs and hospital beds and commodes require simple instruction and education and can be used easily and intuitively by many people with little or no difficulty. Failure to properly use or failure of such medical devices would rarely cause patient harm.

However, some devices used in the home are complex and sophisticated, and their proper operation depends on the competency and capabilities of the home user. The needs, capabilities, and competency of the home user and the suitability of the home environment should be assessed with regards to the use of more sophisticated devices, such as respiratory therapy and intravenous infusion devices. This is especially true for those devices that require higher levels of cognition, memory, and decision-making and/or physical tasks for their proper operation.

Many sophisticated medical devices used for respiratory care such as ventilators, continuous positive airway pressure devices, respiratory disease management devices, apnea monitors and low air loss continuous pressure management devices, require extensive education and instruction or the consequences can be detrimental. The use of these respiratory care devices is governed by the Respiratory Care Practice Act and requires licensure as a respiratory care practitioner, other qualified licensed personnel, or by a person exempted from the Act. Self-care by the patient or the gratuitous care by a friend or member of the family is one of those exemptions.

Furthermore, devices that are not labeled for “over-the-counter” use are not required to be accompanied by training and education for use by non-clinical users. There has been the assumption that the prescribing health care practitioners will assure that such necessary education will be provided to lay caregivers, but in fact, a major problem with the current system is that the education and training of home care users is woefully deficient. Although some home healthcare

organizations do instruct the lay caregivers, it frequently happens that the devices are delivered for use with little or no instruction or supervision by trained professionals.

Some medical devices are handed down from one lay caregiver to another, without the intervention of some supervising health care assessing organization. And this transfer of devices is accompanied by a transfer of information and experience, but there is no guarantee that the information will be accurate and complete. It is also possible that the transferred device itself may not be appropriate for the intended user.

The performance of routine maintenance and repair of medical devices in the home is also acknowledged to be a serious problem affecting the safety and clinical effectiveness of medical devices. Lay caregivers and patients do not necessarily have the knowledge and capability to perform these functions, so the question of who should do this is an unresolved issue.

Manufacturers are ambivalent about the use of their devices in the home. Although presumably the migration of devices into the home increases their markets, it also has significant implications on the safe and effective use of their products. They point to the fact that they are regulated in multiple ways (e.g., by U.S. and foreign regulatory agencies) and they assert that this level of regulatory control provides a large measure of assurance against badly designed devices. But the proper functioning of the device is dependent upon the competency of its user. In the past, doctors, nurses, respiratory therapists and other highly trained health professionals were the users. Now, the world of users is expanding to include lay people, where there is no real assurance about the competency of the user or the suitability of the home environment for the proper functioning of the device.

HOME CAREGIVERS

There are a number of people entering the home, as well as those family members who reside in the home, providing support for home care patients. Many of these home care patients have respiratory ailments and may rely upon sophisticated respiratory equipment for treatment or to sustain life.

Personnel entering homes in support of the home care patient include respiratory care practitioners, registered nurses, vocational nurses, home health aides, and other non-licensed personnel including equipment delivery personnel. There is a vast range of education and experience among these personnel, from people having no familiarity with patient care and/or medical equipment to those that have been educated, trained, and competency tested in patient care and sophisticated respiratory equipment as follows:

Respiratory Care Practitioner [http://www.leginfo.ca.gov/cgi-bin/waisgate?WAISdocID=22452218156+0+0+0&WAISaction=retrieve]

Minimum education: **Associate Degree** (Ref: B&P code, section 3740)

Regulatory agency: Respiratory Care Board of California

Scope of Practice:

Pursuant to B&P code, section 3702:

"...(a) Direct and indirect pulmonary care services that are safe, aseptic, preventative, and restorative to the patient.

(b) Direct and indirect respiratory care services, including but not limited to, the administration of pharmacological and diagnostic and therapeutic agents related to respiratory care procedures necessary to implement a treatment, disease prevention, pulmonary rehabilitative or diagnostic regimen prescribed by a physician and surgeon.

(c) Observation and monitoring of signs and symptoms, general behavior, general physical response to respiratory care treatment and diagnostic testing and

(1) determination of whether such signs, symptoms, reactions, behavior or general response exhibit abnormal characteristics;

(2) implementation based on observed abnormalities of appropriate reporting or referral or respiratory care protocols, or changes in treatment regimen, pursuant to a prescription by a physician and surgeon or the initiation of emergency procedures.

(d) The diagnostic and therapeutic use of any of the following, in accordance with the prescription of a physician and surgeon: administration of medical gases, exclusive of general anesthesia; aerosols; humidification; environmental control systems and baromedical therapy; pharmacologic agents related to respiratory care procedures; mechanical or physiological ventilatory support; bronchopulmonary hygiene; cardiopulmonary resuscitation; maintenance of the natural airways; insertion without cutting tissues and maintenance of artificial airways; diagnostic and testing techniques required for implementation of respiratory care protocols; collection of specimens of blood; collection of specimens from the respiratory tract; analysis of blood gases and respiratory secretions..."

American River College Associate Degree Requirements: 69-70 units. 40 units are directly related to respiratory care: 396 hours lecture and 972 hours clinical practice.

Registered Nurses [http://ccr.oal.ca.gov/cgi-bin/om_isapi.dll?clientID=270884&infobase=ccr&softpage=Browse_Frame_Pg42]

Minimum education: **58 semester units** (ref: CCR, Title 16, Section 1426)

Regulatory agency: California Board of Registered Nursing

Scope of Practice:
Pursuant to B&P code, section 2725:
"...(b) The practice of nursing within the meaning of this chapter means those functions, including basic health care, that help people cope with difficulties in daily living that are associated with their actual or potential health or illness problems or the treatment thereof, and that require a substantial amount of scientific knowledge or technical skill, including all of the following:

(1) Direct and indirect patient care services that ensure the safety, comfort, personal hygiene, and protection of patients; and the performance of disease prevention and restorative measures.

(2) Direct and indirect patient care services, including, but not limited to, the administration of medications and therapeutic agents, necessary to implement a treatment, disease prevention, or rehabilitative regimen ordered by and within the scope of licensure of a physician, dentist, podiatrist, or clinical psychologist, as defined by Section 1316.5 of the Health and Safety Code.

(3) The performance of skin tests, immunization techniques, and the withdrawal of human blood from veins and arteries.

(4) Observation of signs and symptoms of illness, reactions to treatment, general behavior, or general physical condition, and (A) determination of whether the signs, symptoms, reactions, behavior, or general appearance exhibit abnormal characteristics, and (B) implementation, based on observed abnormalities, of appropriate reporting, or referral, or standardized procedures, or changes in treatment regimen in accordance with standardized procedures, or the initiation of emergency procedures..."

American River College Associate Degree Requirements: 67-68 units. 42 units are related to basic nursing and laboratory education (respiratory care is not mentioned): 324 hours lecture and 1,296 hours in clinical practice.

Vocational Nurses [http://ccr.oal.ca.gov/cgi-bin/om_isapi.dll?clientID=270884&infobase=ccr&softpage=Browse_Frame_Pg42]

Minimum education: **1530 hours or 50 semester units** (ref: CCR, Title 16, section 2532)

Regulatory agency: California Board of Vocational Nurse and Psychiatric Technicians

Scope of Practice:
Pursuant to B&P code, section 2518.5:
"...(a) Uses and practices basic assessment (data collection), participates in planning, executes interventions in accordance with the care plan or treatment plan, and contributes to evaluation of individualized interventions related to the care plan or treatment plan.

(b) Provides direct patient/client care by which the licensee:
(1) Performs basic nursing services as defined in subdivision (a);
(2) Administers medications;
(3) Applies communication skills for the purpose of patient/client care and education; and
(4) Contributes to the development and implementation of a teaching plan related to self-care for the patient/client."

College of the Desert Course: 1548 hours in basic nursing: 576 hours of classroom instruction and 972 hours of clinical practice.

Home Health Aides [http://ccr.oal.ca.gov/cgi-bin/om_isapi.dll?clientID=270884&infobase=ccr&softpage=Browse_Frame_Pg42]

Minimum education: **120 hours of training** (ref: CCR, Title 22, Div. 5, Ch. 6, Art. 5, section 74747)

Regulatory agency: Department of Health Services, Home Health Agencies Unit

Scope of Practice:
Pursuant to H&S code, section 1727 and CCR, Title 22, Division 5, Chapter 6, Article 5, Section 74710:
"...(1) Assisting patients with personal hygiene such as skin, mouth, hair care and bathing.

(2) Assisting patients in and out of bed and assisting with ambulation.
(3) Assisting with prescribed exercises which patients and aides have been taught by appropriate health personnel.
(4) Preparing meals, including therapeutic diets, and assisting patients with eating.
(5) Assisting patients to the bathroom or in using commodes, bedpans or urinals..."

College of the Desert Course: 120+ course with 27 hours of classroom instruction and 27 hours of supervised clinical experience directly related to home health care.

Non-licensed personnel *in the Home*

Minimum education: **none**
Regulatory agency: Department of Health Services, Home Health Agencies Unit

Equipment delivery personnel

Minimum education: **none**
Regulatory agency: Department of Health Services, Home Medical Device Retail Facilities Unit

While the course load for minimum education for licensure as a RN is nearly the same as a RCP, the component of respiratory care is only touched upon in a nursing program. A study conducted by the Indiana University found that the entry-level RN, will have had extremely limited didactic instruction in the 15 typical respiratory therapy procedures included in the survey [**Attachment 2**]. "The significance of that difference is magnified when compared to respiratory therapy programs... Factoring in the number of programs that do not even address some of these respiratory therapy tasks, there should be real concern about arbitrarily transferring respiratory care responsibilities in the clinical setting...." In comparing these "15 typical respiratory therapy procedures," it was found that the "mean" time spent teaching "mechanical ventilators" was:

Classroom Hours	Lab Hours	Clinical Hours	
1.6	.71	10.2	in the Associate Degree Nursing Programs;
2.2	1.30	41.5	in the Diploma (3-year) Nursing Programs;
1.5	.72	14.9	in the Baccalaureate Degree Nursing Programs, and
44.8	33.00	227.8	in the Respiratory Therapy Program.

The "mean" time spent teaching "oxygen therapy" was:

Classroom Hours	Lab Hours	Clinical Hours	
2.4	1.8	21.2	in the Associate Degree Nursing Programs;
2.7	1.5	68.7	in the Diploma (3-year) Nursing Programs;
2.46	2.0	24.4	in the Baccalaureate Degree Nursing Programs, and
18.69	13.2	67.37	in the Respiratory Therapy Program.

The study found that "it is clear that entry-level nurses who do not obtain significant postgraduate education cannot perform respiratory care procedures." Furthermore, LVNs have even less minimum education requirements, and experience in itself is not sufficient to fully comprehend all aspects of respiratory care.

RCPs are the only health care professionals who receive formal education, clinical training, and validated competency testing in respiratory care. The minimum education required of California RCPs is slightly more than that required of RNs. However, a RCPs education is strictly focused on all aspects of respiratory care. There are approximately 120,000 RCPs nation-wide and 15,000+ in California alone.

REGULATION IN CALIFORNIA

The "home" is a unique setting for medical care which is incredibly difficult to regulate compared to care provided in a managed facility (i.e. hospital, skill nursing facility, etc...). Currently in California, regulation is limited to Home Medical Device Retail Facilities and Home Health Agencies. Neither component recognizes the need for formal education, training and competency testing as it pertains to respiratory care and the use of respiratory medical devices.

It is important to note that the regulation of Home Medical Device Retail Facilities is under the Food and Drug Branch of the Department of Health Services. The regulation of Home Health Agencies falls under the Licensing and Certification Branch of the Department of Health Services. Each unit is independent from one another.

Home Medical Device Retail Facilities (**HMDRFs**)

In 1987, legislation (1997 statutes, ch. 1115) passed which required all Medical Device Retailers to become licensed by California's Board of Pharmacy no later than July 1, 1991. Nine years later, in 2000, legislation (2000 statutes, ch. 837, AB 1496) passed which transferred the regulatory control of Medical Device Retailers from the Board of Pharmacy to the Department of Health Services (**DHS**) effective January 1, 2002. This legislation also expanded the regulatory oversight to include dispensing of oxygen, hospital beds and wheelchairs. Thus, a new licensure category, HMDRF, was created. Current California laws and regulations governing HMDRFs are included in **Attachment 3.**

Section 109948 of the Health and Safety Code defines a "Home Medical Device Retail Facility" as, "an area, place, or premises, other than a licensed pharmacy, in and from which prescription devices, home medical devices, or *home medical device services* are sold, fitted, or dispensed pursuant to prescription..."

"Home medical device services" is defined by section 109948.1 (a) as the "delivery, installation, maintenance, replacement of, or instruction in the use of, home medical devices used by a sick or disabled individual to allow the individual to be maintained in a residence."

Loosely interpreted, the definition of "home medical device services" could lead one to believe that "instruction in the use of, home medical devices...to allow the individual to be maintained in a residence" includes operating and/or adjusting settings on medical devices as prescribed. However, the operation of or adjustment of settings on medical devices, whether to a prescription or otherwise, for the purpose of deriving a medical benefit, is providing patient care; care which is not authorized or regulated under the regulation of HMDRFs and care that is governed by the Respiratory Care Practice Act.

In a meeting with the DHS's HMDRF unit in July 2003, it was noted that due to budget restraints the unit is grossly understaffed and has been forced to prioritize its workload. The HMDRF unit stated that 1200 HMDRFs have filed an application for licensure but that there are an estimated 2400 more HMDRFs who have not complied with the law to become licensed by January 2002. The HMDRF unit confirmed that it is unable to conduct annual inspections for all licensees as required by law due to staffing shortages. They also confirmed that the focus of initial inspections is to ensure equipment is sanitized and stored properly, and proper dispensing personnel (as defined by the law) are hired.

According to section 111635, "the department shall conduct these inspections to determine ownership, adequacy of facilities, and personnel qualifications." However, inspections of "personnel qualifications" is limited to showing evidence that an employee has been "trained" to understand the operation of the device. Generally, evidence of "training" consists of a certificate of completion from either an in-service session or manufacturer's course on specific equipment. There is no requirement to evaluate competency or consider personnel qualifications as it relates to the care or well being of the patient. Further, because licensure of HMDRFs stops at the instruction in the use of equipment, there is no inspection related to personnel qualifications in providing care.

However, the HMDRF unit has been working with the Board by investigating complaints of unlicensed practice at the time of scheduled inspections. The HMDRF unit has immediate access to records and employees that would allow them to substantiate a complaint of unlicensed practice. Though, because of limited resources, complaints can take months or even years to be investigated.

Many HMDRFs concerned for patient safety and who understand the liabilities of not having a trained professional have taken it upon themselves to hire licensed RCPs to provide set-up, instruction and consultation as needed. These HMDRFs receive no compensation for RCP services. In addition, many of these same reputable HMDRFs provide free consultation to nurses, who are the home caregivers, in crises. Though the nurses have no affiliation with the HMDRFs, the HMDRFs feels compelled in the interest of patient safety to provide free consultation in respiratory care and the operation of respiratory medical devices.

However, some HMDRFs are employing equipment delivery personnel to perform patient care, including the performance of ventilator checks and medication delivery. Equipment delivery personnel are not qualified to perform any type of clinical assessment or care. Rather, they should be limited to delivering equipment, setting up the equipment (not to the patient), and instructing how to operate the equipment from a mechanical perspective. They are not qualified or authorized to adjust settings for a patient. Even then, there are reports that drivers are delivering oxygen cylinders improperly such as placing tanks next to gas pilot lights; a perfect combination for a fatal disaster. There are also numerous reports of fraud emerging specifically that HMDRFs are ordering additional tests without a physician's order and billing for additional and unnecessary equipment. Many HMDRFs have been using equipment delivery personnel to conduct these respiratory diagnostic tests which are the basis for renting additional equipment.

Home Health Agencies (**HHAs**)

Unlike the regulation of HMDRFs, HHAs are mandated to provide patient care. It is believed that regulation of "patient care" has made the unsafe practice of respiratory care less prevalent among Home Health Agencies. Furthermore, Federal legislation (H.R. 2905 & S. 2707), if enacted, will increase consumer protection by recognizing "respiratory therapists" as a provider for skilled visits (discussed in greater detail in following pages).

Section 1727 of the Health and Safety Code defines a HHA as a "private or public organization, including, but not limited to, any partnership, corporation, political subdivision of the state, or other government agency within the state, which provides, or arranges for the provision of, skilled nursing services, to persons in their temporary or permanent place of residence."

"Skilled nursing services" is defined in this section as "services provided by a registered nurse or licensed vocational nurse." HHAs also uses certified Home Health Aides to provide personal care services (i.e. bathing, personal hygiene, meals, etc...) and other non-licensed personnel to perform other services of the treatment plan. California laws and regulations governing HHAs are included in **Attachment 4.**

HHAs are required to maintain, and implement policies regarding the storage, furnishing, and transportation of durable medical equipment. HHAs have always held an exemption from licensure for medical equipment whether from previous regulation of Medical Device Retailers or current regulation of Home Medical Device Retail Facilities.

HHAs are required to have a RN, or occupational, physical, or speech therapist oversee all treatment plans (within each professional's scope of practice). Generally, a RN will oversee the treatment plan of a patient with respiratory ailments. However, care may be performed by a LVN, home health aide or "other non-licensed personnel."

While it is believed that problems with untrained and unqualified personnel providing care is more serious with HMDRFs there is still concern for care provided through HHAs. The most common complaint received regarding HHAs is that the staff whether it be licensed or non-licensed personnel are not familiar with respiratory medical equipment and are not educated to respond to unusual situations. Furthermore, the staff are not educated or trained on how to use the medical equipment to allow the patient to receive the most beneficial treatment.

Some HHAs hire RCPs because, like some HMDRFs, they strive to provide optimal patient-care and they see the benefit of having an expert on staff to address respiratory problems and oversee respiratory medical devices, though only limited reimbursement for RCP services is provided. (Note: currently there is Federal legislation (H.R. 2905/S. 2707), supported by numerous associations, that would recognize services provided by RCPs as "skilled visits" under the Medicare home health services benefit which will alleviate concerns in this area [S. 2707 can be viewed at: [http://thomas.loc.gov/cgi-bin/query]

NATIONAL HOME CARE ACCREDITATION

There are three recognized private home care accreditation agencies at the national level. One such well known agency is the Joint Commission on Accreditation of Healthcare Organizations (**JCAHO**) who accredits over 17,000 healthcare organizations, including writing applicable standards and evaluating adherence to them. Home medical retailer accreditation is voluntary, and the organization seeking accreditation pays for this service. Currently over 4,300 home care agencies/device retail facilities are accredited by JCAHO, but this is only 25% of home care providers nation-wide.

JCAHO's accreditation process involves on-site visits at least once every three years, and JCAHO may put a facility on probation or remove an accreditation for violation of pertinent standards. Part of JCAHO's survey process is to determine which, how and by whom services are being provided. JCAHO interviews drivers, patients, customer service representatives, and management and reviews company and patient records. JCAHO also does "ride-alongs" and asks patients and caregivers to demonstrate their ability to use the equipment.

In addition to the disincentive of cost, there are few incentives for suppliers to seek accreditation by JCAHO, since accreditation is not required by the Centers for Medicare and Medicaid Services (CMS) or by third party payers. JCAHO currently does not have agreements with states to supplant state licensing of medical device retailers. Additionally, organizations that contract with providers do not all require accreditation.

To be licensed as a Home Health Agency in California, the HHA may qualify for licensure if it is accredited as a home health agency by either the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or the Community

Health Accreditation Program (CHAP). The accrediting organization must forward to the DHS copies of all initial and subsequent surveys and other accreditation reports or findings [ref: H&S Code, section 1728.7 (1)]. HMDRFs have no such alternative for licensure.

However, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) provides that all durable medical equipment suppliers must be accredited in order to qualify for reimbursement. The time frame for implementation has not yet been determined, though more information is expected to surface by 2007 [ref: http://www.cms.hhs.gov/medicarereform/issueoftheday/03192004iotd.pdf or pgs. 158-168 http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=108_cong_bills&docid=f:h1enr.txt.pdf]

CONSIDERATIONS

HMDRFs and Patient Care

Unlicensed personnel employed by HMDRFs who dispense equipment affecting the respiratory system are providing patient care. In addition to reports of such activities, it would be unreasonable to think that a HMDRF would dispense a sophisticated device by simply explaining to a caregiver who has no medical background, how to turn the machine off and on and explain the many facets of the device. The reality is that HMDRFs are dispensing sophisticated devices and then providing care by adjusting settings as prescribed and providing consultation to the family to not only include how the machine operates but also in reference to treatment of the patient.

Moreover, there is no such thing as zero defects. Unintentional situations will always occur, even under the best of circumstances, and with the best processes of design, manufacture, and implementation. Thus, there will always be risks involved with the use of medical devices, whether in the home or in the hospital. Unlicensed personnel do not have the education and training needed to respond to crises.

Following is an example of the steps taken by HMDRFs to transfer a ventilator patient from a hospital to the home, at the request of the hospital, where family members will be providing the care. This particular scenario was provided by a HMDRF who uses licensed RCPs, rather than unlicensed personnel, to provide all instruction, perform the transfer, and provide follow up consultation.

- For a period of two weeks prior to the release of the ventilator patient, a RCP reports to the hospital each day and instructs the family in the operation of the equipment.
- On the day the patient is transferred to the home, a ventilator will be at the home and arrangements are made so that the RCP arrives at the same time transportation, generally an ambulance, arrives with the patient.
- Upon the patient's arrival, the RCP makes the necessary ventilator adjustments, removes the patient from the ventilator used while in transport, and connects the ventilator at home to the patient. This step alone takes the definition of "medical device services" including "instruction in the use of" to its extreme and crosses over into patient care requiring a professional with formal education and training and who is competency tested.
- The RCP continues to visit the home daily for a week. And then gradually reduce to every other day until only monthly visits are made.

Clinical guidelines prepared by the American Association for Respiratory Care and adopted by the Respiratory Care Board provide, in part, guidelines for "Patient-Ventilator System Checks" (http://www.rcjournal.com/online_resources/cpgs/mvsccpg.html). These guidelines show the numerous steps involved in simply "checking" ventilators and patients. Clearly, one would need formal education and training and should be competency tested, such as completed by RCPs, in order to ensure competent performance of these tasks. Such unlicensed practice is considered a violation of the Respiratory Care Practice Act.

Long-Term Oxygen Therapy

Another factor to consider is the dispensing of oxygen cylinders, one of the most frequently dispensed devices. Although the handling of oxygen is not required to be done by a licensed professional, the HMDRF must ensure personnel handling oxygen are trained. Again, nothing more than a certificate of completion is needed for purposes of regulation. Licensed professionals (i.e. RCP, RN, LVN) receive formal education and training on the handling of hazardous materials. There have been several warnings issued in relation to the improper handling of oxygen and medical gas mix-ups resulting in unnecessary fatalities **(Attachment 5)**. Due to continual injuries that occur from improper handling it would be beneficial to have a licensed professional, who has both education and training in this area, on staff for consultation.

Moreover, a study conducted by three physicians, titled "Implementation of an Oxygen Therapy Clinic to Manage Users of Long-Term Oxygen Therapy" revealed significant cost savings and improved patient outcomes when using a RCP as part of the treatment plan **(**http://www.chestjournal.org/cgi/content/full/122/5/1661**).** The study notes that the majority of initial oxygen prescriptions are for patients being discharged from the hospital whose oxygen requirements are not stable.

The study evaluated the benefits of home visits by a respiratory therapist and found that 40.5% of patients did not meet criteria for Long-Term Oxygen Therapy (**LTOT**). Furthermore, it was found that LTOT could be discontinued in more than one third of patients who had existing oxygen prescriptions.

The study also looked at potential benefits of a hospital-based home-care program in Chronic Obstructive Pulmonary Disease (COPD) patients receiving LTOT. This intervention consisted of monthly telephone calls and visits every 3 months. It was found that there was a significant decrease in emergency department visits, hospital admissions, and lengths of hospital stays.

The study concluded that, "results of this initial evaluation suggest that the institution of a respiratory therapist-managed oxygen therapy clinic to manage home oxygen patients can significantly decrease inappropriate supplemental oxygen use, which can result in significant cost savings while providing improved health-care delivery."

REPORTING SUBSTANDARD CARE

The home user is notoriously a poor reporter of device malfunctions or substandard care. While the legislation which transferred the regulatory oversight of Device Medical Retailers was being considered, the Board of Pharmacy noted that in the eight years it licensed Medical Device Retailers, it had not received any complaints from patients. Rather, the board stated their sole enforcement activities included the investigation of complaints of unlicensed activity made by other medical device retailers.

Poor reporting by home care patients and family can be attributed to many things including, the misguided trust that the State is regulating the caregivers, the lack of knowledge that the caregiver is providing substandard care, the misunderstanding that all caregivers who enter the home have the same qualifications, lack of awareness that certification and licensure exists, the lack of awareness of the breadth of each caregiver's training, education or scope of practice, or the fear that a report may have negative repercussions for the home care patient.

REPORTING INJURIES/DEATHS ASSOCIATED WITH MEDICAL DEVICES

In 1990, the Safe Medical Devices Act passed, requiring nursing homes, hospitals, and other facilities that use medical devices to report to FDA incidents that suggest that a medical device probably caused or contributed to the death, serious illness, or serious injury of a patient.

Through a variety of information-gathering mechanisms, FDA is aware that deaths and serious injuries are sometimes associated with the use of medical devices, and there are device malfunctions that can and do occur which could lead to death and serious injury. Despite efforts by manufacturers and the FDA to mitigate these problems whenever possible, the risk of unintended side effects from the use of medical devices is an ever-present reality. These sorts of problems occur even with the use of medical devices by trained health practitioners in controlled health care delivery environments, but FDA believes that the use of sophisticated medical devices in the home environment adds an additional level of risk of unintended adverse events. This is not to imply that the use of these devices should be prohibited in the home environment, in order to reduce this additional risk; indeed such a strategy would be practically impossible given the way that health care has evolved. But it is FDA's intention to seek ways of improving the safety and effectiveness of these devices.

Anecdotal reports of patient deaths or injuries as a result of problems with these factors are increasing. You can access many of these reports on-line at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM where you will find the Manufacturer and User Facility Device Experience Database (**MAUDE**). There are hundreds if not thousands of reports where injuries and deaths have occurred in connection with medical devices. Unfortunately, these are simply reports with generally no further investigation as to the cause of death or injury other than inspection and testing of the medical device in question, if the device can even be retrieved. In reviewing some of these reports, consideration is given to whether or not these events could have been prevented and whether or not proper training and instruction was given or if access to a RCP was made available (**Attachment 6**).

REIMBURSEMENT

In addition to regulatory controls, reimbursement, or the lack of it, drives the existing home care practice. The California's Office of Administrative Law website identifies California reimbursement criteria and rates for homecare related services and equipment [ref: http://ccr.oal.ca.gov/] As of September 2, 2003, they provide, in summary, reimbursement as follows:

Home Health Agencies [ref: Title 22, Division 3, sections 51523 and 51337]

* Skilled Nursing Services (RN or LVN)	$74.86/hour
* Home Health Aide Services	$45.75/2 hours
* Physical Therapy Services	$68.48/hour
* Occupational Therapy Services	$71.36/hour
* Speech Therapy Services	$78.43/hour
* Unlisted Services	By report/prior authorization required

* One visit in a six-month period for evaluation of the patient is covered without prior authorization.
* A maximum of 30 visits may be authorized at any one time and authorizations shall be valid for up to 120 days.

Home Medical Device Retail Facilities [ref: Title 22, Division 3, section 51521]

* Various reimbursement rates for the following equipment are provided:
  1) Canes and Crutches
  2) Walkers
  3) Bathroom Equipment
  4) Antidecubitus Care (ADC) Support Surfaces, Equipment, and Supplies
  5) Hospital Beds and Accessories
  6) Traction and Trapeze Equipment
  7) Oxygen and Oxygen Therapy Equipment
  8) Wheelchairs, Modifications, and Accessories
  9) Infusion Equipment and Supplies
* Maximum reimbursement rates for equipment *include* 1) freight, delivery, transportation 2) installation, setup and instruction in the use of equipment, and 3) repair, maintenance or routine servicing (some maintenance may be reimbursed on an exception basis).

A white paper issued by the American Association for Respiratory Care titled, *Cost-Effectiveness of Respiratory Care* **(Attachment 7)**, illustrates the savings that could be realized if respiratory therapists were reimbursed for their services in the home setting. Literally, millions of dollars could be saved by using a respiratory therapist to treat respiratory ailments in the home.

The Federal government is just beginning to recognize that the practice of respiratory care is a specialized field. The benefits of respiratory treatment by a licensed RCP improves patient care and has financial incentives for health insurers.

On July 28, 2003, bill number H.R. 2905 was introduced in the U.S. House of Representatives. On July 21, 2004, bill number S. 2707 was introduced in the Senate. Both bills would amend the Social Security Act to recognize the services of respiratory therapists under Medicare's home health services benefit. These bills would not have any impact on payment, but rather add respiratory therapists to the list, similar to that noted above under Home Health Agencies, as one of the providers that may be reimbursed for respiratory care. The Home Healthcare Nurses Association and the National Association for Home Care have issued letters in support of this legislation. Because HHAs are specifically established to provide patient care, the problem of inadequate patient care is not as common among HHAs. If enacted, this bill will increase consumer protection by making it an incentive for HHAs to provide optimal care for respiratory ailments which will likely lead to a decline in emergency room visits, shorten lengths of stays, and avoid readmissions. Yet it does not address reimbursement made by the State or the practice of respiratory care occurring through HMDRFs.

Further perpetuating problems with HMDRFs, is the reduction in reimbursement rates that occurred as part of the State's 2003-2004 State budget. A trailer bill (2003 statutes, AB 1762, chapter 230) to the 2003-2004 Budget made significant reductions to reimbursement for durable medical equipment). AB 1762 provides that reimbursement for durable medical equipment shall be reduced to 80% of the lowest maximum allowance for California established by the federal Medicare program (or any other lower rate as described. It further provides that reimbursement for monthly rental charges shall cease after 10 months. Thereafter, the provider shall continue to provide the equipment without charge until the medical necessity ends or Medi-Cal coverage ceases.

As previously mentioned, there are many reputable HMDRFs and HHAs who recognize the legal requirements as well as the benefits of using a RCP in the interest of patient safety and optimal patient outcomes, regardless of the fact that they do not receive reimbursement. Yet it is believed that the majority of providers are driven more by financial gain rather than patient care. Therefore, because there is no clear mandate to require the use of, and no reimbursement for services provided by, a RCP, many HHAs and HMDRFs do not hire them and the potential for costs savings while providing optimum care is negated.

RESPIRATORY CARE BOARD MANDATE AND ACTIONS

The Respiratory Care Board of California (Board) is mandated to protect the public from the unauthorized and unqualified practice of respiratory care and from unprofessional conduct by persons licensed to practice respiratory care. It is further mandated that "protection of the public shall be the highest priority for the Respiratory Care Board of California in exercising its licensing, regulatory, and disciplinary functions."

In response to information that unlicensed personnel employed by HMDRFs were exceeding their purview and entering the realm of respiratory care, the Board stated its position in its January 2002 newsletter and issued it to all licensed HMDRFs. The Board stated that, "The delivery of [respiratory] equipment does NOT include application of the equipment to a patient or instruction in the use of the equipment for the purpose of deriving the intended medical benefit. Such services are the practice of respiratory care."

In addition, the Board sponsored legislation which became effective January 1, 2003, that allows the Board to cite and fine an individual for unlicensed practice. However, as noted under "Reporting" the "home user is a notoriously poor reporter." And should reports be received, the Board has limited resources to expend on complex investigations where evidence may not even be available or witnesses may not choose to cooperate. The Board has had cases where "owners" of a small family-run business were allegedly providing respiratory care and obtaining supporting evidence was unsuccessful. Consideration is being given to "sting" operations which would have limited benefits, but the Board does not have the resources to perform such operations on a regular basis. Moreover, the Board has no authority or resources to conduct routine inspections as done by the Department of Health Services.

RECOMMENDATIONS

I. RESPIRATORY CARE BOARD
PROPOSED LEGISLATIVE & REGULATORY AMENDMENTS

A. Proposed Law/Legislative Amendments

The Board recommends the following proposed legislative amendments as a means to provide guidance to the home care industry, through regulation, of what services a "delivery driver" or other unlicensed personnel may perform and under which criteria, as it relates to respiratory care and respiratory care related services. Proposed amendments also provide clarification and give notice for anyone practicing respiratory care through an exemption of their obligations to provide information to the Board and actions the Board can take should one exceed the purview or requirements for the exemptions provided. (The addition to subsection (4) is for clarification purposes.)

> Underline delineates "new" proposed language to be added to section 3765 of the Business and Professions Code ("law" in the Respiratory Care Practice Act).

§ 3765. Acts not prohibited

(a) This act does not prohibit any of the following activities:

~~(a)~~ (1) The performance of respiratory care which is an integral part of the program of study by students enrolled in approved respiratory therapy training programs.

~~(b)~~ (2) Self-care by the patient or the gratuitous care by a friend or member of the family who does not represent or hold himself or herself out to be a respiratory care practitioner licensed under the provisions of this chapter.

~~(c)~~ (3) The respiratory care practitioner from performing advances in the art and techniques of respiratory care learned through formal or specialized training.

~~(d)~~ (4) The performance of respiratory care by paramedical personnel, in an emergency situation, who have been formally trained in these modalities and are duly licensed under the provisions of an act pertaining to their speciality.

~~(e)~~ (5) Respiratory care services in case of an emergency. "Emergency," as used in this subdivision, includes an epidemic or public disaster.

~~(f)~~ (6) Persons from engaging in cardiopulmonary research.

~~(g)~~ (7) Formally trained licensees and staff of child day care facilities from administering to a child inhaled medication as defined in Section 1596.798 of the Health and Safety Code.

(8) Persons, employed by a Home Medical Device Retail Facility or a Home Health Agency licensed by the Department of Health Services, from performing specific limited and basic respiratory care or respiratory care related services, under certain conditions, as identified by the Board.

(b) Any employer, facility, company, corporation, organization, contractor or person which the Board suspects may be providing respiratory care services by unlicensed personnel, which are not otherwise exempt from this chapter, shall allow for inspections and provide documentation and reports and be subject to administrative fines for failure to do so as provided in subdivisions (a) and (b) of section 3717.

(c) The unlicensed practice of respiratory care or employing or contracting with unlicensed personnel to provide respiratory care, unless otherwise exempted by this chapter, is prohibited and subject to administrative citation and fine or discipline, criminal, civil and/or any other remedies as provided in this chapter.

Added Stats 1982 ch 1344 §§ 1, operative July 1, 1983. Amended Stats 1991 ch 654 §§ 36 (AB 1893). Amended Stats 1998 ch 625 §§ 1 (SB 1663). Amended Stats 2006 ....

B. Proposed Regulatory Amendments

The Board recommends the following proposed regulatory amendments as a means to interpret and make specific the proposed legislative amendment above. These proposed amendments provide specific and needed direction for Home Medical Device Retail Facilities and Home Health Agencies.

The following proposed section, section 1399.360, is "new" and proposed for adoption in the California Code of Regulations, Title 16, Division 13.6 (respiratory care section).

Article 6. Respiratory Care Practice
1399.360. Unlicensed Personnel Services; Home Care

(a) Persons, not otherwise authorized or exempt to provide respiratory care services as provided in the Act, may perform limited and basic respiratory care or respiratory care related services identified in subdivisions (b), (c) and (d), in the home setting or for the purposes of patient transfer to the home setting, provided the following conditions are met:

(1) The person is providing services through his/her employment with a Home Medical Device Retail Facility or Home Health Agency licensed by the California Department of Health Services (or subsequent regulatory name and/or agency);

(2) Initial training, ongoing in-service education, and periodic competency testing specific to each service and equipment-type is provided by either a California licensed respiratory care practitioner (as appropriate to the specific training, in-service and testing) or other qualified licensed personnel (HMDRF Exemptee) and documentation of such training, education and testing is maintained for a period of four years, and

(3) Each patient or caregiver, as appropriate, is advised prior to or at the time equipment or supplies are delivered, and such services are provided accordingly, that a licensed respiratory care practitioner or other qualified licensed personnel of the equipment provider shall provide follow up checks, by telephone or in-person as appropriate, at the request of the patient, the patient's physician, the patient's caregiver, or any person who has had contact with the patient, or as otherwise directed by a plan of care.

(b) In accordance with this section and as it relates to:

* positive airway pressure (with or without a back-up rate) devices and supplies;
* intermittent positive pressure breathing devices and supplies;
* ventilatory devices and supplies;
* nasotracheal or tracheal suctioning devices and supplies;
* apnea monitors and alarms and supplies;
* tracheostomy care devices and supplies;
* respiratory diagnostic testing devices and supplies, including but not limited to pulse oximetry, CO2 monitoring, and spirometry devices and supplies, and
* pulse-dose type or demand conserving oxygen delivery devices or high flow oxygen systems beyond the capabilities of a simple mask or cannula or requiring particulate or molecular therapy in conjunction with oxygen,

(1) Unlicensed personnel may:

(A) Deliver equipment and supplies, and

(B) Instruct the patient or the patient's family or caregiver(s) on how to order equipment and supplies and where to call, 24 hours a day, 7 days a week, in case of emergency.

(2) Unlicensed personnel are prohibited from:

(A) Setting up equipment;

(B) Providing any instruction to the patient or patient's family or caregiver(s) as it relates to the operation or use of the equipment, clinical application of the equipment and/or supplies;

(C) Performing any level of clinical assessment of the patient;

(D) Touching the patient for the purposes of making an assessment or placing any device upon the patient, and

(E) Any other interaction with the patient or the patient's family or caregiver(s) that is not described in subsection (b) (1).

(c) In accordance with this section and as it relates to oxygen delivery systems and prefilled cylinders, excluding pulse-dose or demand conserving oxygen systems and high flow oxygen systems beyond the capabilities of a simple mask or cannula or requiring particulate or molecular therapy in conjunction with oxygen,

(1) Unlicensed personnel may:

(A) Deliver equipment and supplies;

(B) Instruct the patient or the patient's family or caregiver(s) on how to order oxygen equipment and supplies and where to call, 24 hours a day, 7 days a week, in case of emergency;

(C) Instruct the patient or the patient's family or caregiver(s) in the proper and safe operation of oxygen equipment including:

(i) equipment set-up;

(ii) connecting disposable tubing, cannulas, and masks;

(iii) verification of oxygen flow;

(iv) demonstration to the patient of prescribed flow rate(s);

(v) connection and cleaning of oxygen humidifying equipment and devices;

(vi) use of portable back-up oxygen cylinders and equipment, and

(vii) removal and disposition of disposable tubing, cannulas, and masks, and

(D) Conduct regular in-home evaluations and gather information from the patient and home setting pertaining to the set-up, instruction, and provision of information as described in this subdivision for the use of the prescribing physician.

(2) Unlicensed personnel are prohibited from:

(A) Direct administration of home oxygen;

(B) Handling or adjusting home oxygen equipment while it is in use by the patient or on the patient;

(C) Touching the patient or placing any device upon the patient while engaged in the set-up and instruction of equipment, including performing an oximetry evaluation or oxygen saturation test;

(D) Directly engaging in any changes of the set-up, instruction or use of oxygen or explanation of therapy, clinical care plans, prescribed equipment and/or clinical applications, and

(E) Any other interaction with the patient or the patients' family or caregiver(s) that is not described in subsection (c) (1).

(d) In accordance with this section and as it relates to respiratory care equipment and supplies not identified in subdivisions (b) and (c),

(1) Unlicensed personnel may:

(A) Deliver equipment and supplies;

(B) Instruct the patient or the patient's family or caregiver(s) on how to order equipment and supplies and where to call, 24 hours a day, 7 days a week, in case of emergency;

(C) Set up equipment, and

(D) Provide instruction to the patient or the patient's family or caregiver(s) of the:

(i) mechanical operation of the equipment or

(ii) the general use of equipment or supplies.

(2) Unlicensed personnel are prohibited from:

(A) Performing any level of clinical assessment of the patient;

(B) Providing any instruction to the patient or the patient's family or caregiver(s) as it relates to the:

(i) operation or use of the equipment for the purpose of deriving the intended medical benefit or

(ii) clinical application of equipment and/or supplies;

(C) Directly engaging in any discussion of clinical care plans, therapy, prescriptions, or clinical application;

(D) Touching the patient or placing any device upon the patient while engaged in the set-up and instruction of equipment, and

(E) Any other interaction with the patient or the patients' family or caregiver(s) that is not described in subsection (d) (1).

Authority: Business and Professions Code, Section 3722 and 3765. Reference: Business and Professions Code Sections 3701, 3702, 3703, 3704, 3705, 3706, 3717, 3731, 3760, 3761, 3762, 3763, 3764, 3765, 3766, 3767, 3768, and 3778 and Health and Safety Code Sections 1725, 1726, 1727.1, 109948, 109948.1, 111656, and 111656.3.

III. RECOMMENDED DEPARTMENT OF HEALTH SERVICES (DHS) HOME MEDICAL DEVICE RETAIL FACILITIES (HMDRF) LEGISLATIVE AMENDMENTS

A. Expand DHS' Authority to Ensure Safe Practice and Enforce Violations

The Board recommends that the DHS be given broader regulatory control over Home Medical Device Retail Facilities so that it can also ensure patient safety. Specifically, the Board is recommending that the DHS be required to ensure HMDRFs dispensing respiratory equipment or supplies, are providing safe respiratory care, in accordance with the proposed Respiratory Care Board guidelines above, and have the means and authority to enforce such requirements. HMDRFs could be required to report they are aware of the regulations governing the delivery, set-up, and instruction in the use of respiratory care equipment and/or supplies and routine checks of compliance could be included at the time of annual inspections.

B. Accreditation as a Condition of Licensure

The Board recommends that the DHS review and consider requiring all HMDRFs providing any respiratory care device or supplies to hold accreditation by a nationally-recognized accrediting agency (i.e. Joint Commission on Accreditation of Health Care Organizations, the Accreditation Commission for Healthcare, or the Community Health Accreditation Program) as a condition for HMDRF licensure.

Guidelines provided to the accrediting agencies for use when reviewing or inspecting HMDRFs could include H&S Code requirements as well as those provided in the Respiratory Care Practice Act. The accrediting body should also be required to provide all inspection reports, data, information or other reports to the DHS or other state agency upon request.

Throughout the H&S Code there are several references to the DHS using accrediting agencies in some aspect from using accreditation as a pathway for licensure as a Home Health Agency, to the nearly complete oversight of outpatient clinics to providing inspections for health care facilities (ref: H&S Code, sections 1728.7 (1), 1248.1, 1282). Requiring accreditation as a condition for licensure would take advantage of valuable resources saving the State costs and improving the effectiveness of State regulation. Due to limited resources with the DHS and the proven effectiveness and recognition of national accrediting agencies, this alternative would provide profound financial and consumer safety incentives for the State.

HME News [http://www.hmenews.com/2003.08/depts/news/topstory1.htm] reports that of 115 respondents, 51% favored mandatory accreditation. The newsletter noted that most national home medical equipment companies believe a mandatory requirement for accreditation has merit.

C. Require Employment of Licensed RCP or Other Qualified Licensed Personnel

The Board recommends that all HMDRFs who dispense home medical equipment as defined in Health and Safety Code, section 109948.1, subdivision (b), with the exception of hospital beds and commodes, electronic and computer driven wheelchairs and seating systems, transcutaneous electrical nerve stimulator, in vitro diagnostic tests, and other non-respiratory related equipment and supplies, be required to employ a licensed respiratory care practitioner or other qualified licensed individual working under the direction of a California licensed physician. The Board recommends that this requirement be a condition of initial licensure and license renewal and that the DHS have the authority to take administrative action for violations of this requirement. This proposed requirement would reduce fraud among the home care industry and significantly improve patient care, thereby reducing costs for hospital emergency room visits and readmissions.

D. Emergency Contact Requirement

The Board recommends that as a condition for licensure as a HMDRF, a RCP or qualified RN should be required to be available 24 hours a day, 7 days a week for urgent response when that HMDRF dispenses specific medical devices and where a Home Health Agency, private RCP or RN is not employed and patients should be properly notified of such service. This recommendation may provide cost savings as it provides an alternative to emergency room visits and hospital readmissions for situations that may be corrected or addressed by the HMDRF. It also provides a comfort measure and an additional safety mechanism to patients and patients' families who may hesitate to make a visit to the emergency room but after contacting the HMDRF, may have a situation requiring the immediate attention by the HMDRF or emergency care .

IV. RECOMMENDED DHS HOME HEALTH AGENCY LEGISLATIVE AND/OR REGULATORY AMENDMENTS

A. Recognize Respiratory Therapist Services

The Board recommends that sections 1727.1 and 1727.5 of the Health and Safety Code be amended to provide clarification and support proposed reimbursement options (noted below), with no cost impact, as follows:

1727.1. A licensed home health agency may also provide, or arrange for the provision of, other therapeutic services to persons in their temporary or permanent place of residence. Therapeutic services include, but are not limited to, physical, respiratory, speech, or occupational therapy, medical social services, and home health aide services.

1727.5. Each home health agency providing home health agency services shall do all of the following:
(a) Provide for a plan of treatment for patients receiving skilled nursing services.
(b) Maintain clinical records on all patients.
(c) Provide for the supervision of licensed and unlicensed personnel by a registered nurse or physical, respiratory, speech, or occupational therapist when within the therapist's scope of practice.
(d) Maintain policies regarding the delivery and supervision of patient care that are reviewed annually by a group of professional personnel including a physician and surgeon and a registered nurse and revised as needed.
(e) Meet all applicable federal, state, and local requirements.
(f) Maintain, and revise as needed, and implement policies regarding the purchase, storage, furnishing, and transportation of legend devices that are reviewed annually by a group of professional personnel, including a physician and surgeon, pharmacist, and a registered nurse. As used in this subdivision, "legend devices" means any device that bears the label "Caution: federal law restricts this device to sale by or on the order of a ____" or words of similar meaning.
(g) Meet other standards, rules, and regulations adopted by the state department in order to implement this chapter.

These proposed amendments would provide clarification that a licensed home health agency may provide or arrange for respiratory services (as currently done). They also provide respiratory therapists as an additional type of licensed personnel that can provide supervision of personnel, allowing Home Health Agencies more options in providing optimum care for their respiratory care patients. These amendments do not provide for additional services or costs, but rather provide the ability to use the expertise of a respiratory care practitioner in the plan of treatment when it is within the respiratory care scope of practice.

V. CALIFORNIA REIMBURSEMENT REGULATIONS RECOMMENDED LEGISLATIVE AND/OR REGULATORY AMENDMENTS

A. Clean-Up Regulatory Language

In review of this issue, the Board noted section 51224.5 of Division 3 of Title 22 of the California Code of Regulations [Durable Medical Equipment and Medical Supply Providers] needed amendments to properly cite that HMDRFs must be licensed by DHS (or to parallel Medicare reimbursement standards if the above recommendation requiring accreditation was accepted, that HMDRFs must hold accreditation) to receive reimbursement (it appears currently that regulations continue to cite various boards and departments that previously oversaw regulation for each type of equipment, prior to the transfer of all these devices under one regulatory authority of the DHS).

B. Reducing Costs Through HMDRF Follow Up Assessments

The Board recommends that serious consideration be given to establish provisions for the reimbursement of follow-up patient assessments made through HMDRFs [reference CCR section 51523]. Currently, section 51521 of Division 3 of Title 22 of the California Code of Regulations only provides HMDRFs reimbursement for specific types of equipment delivered. Reimbursement for the freight, delivery, transportation, installation, setup and instruction in the use of equipment, and repair, maintenance or routine servicing is inclusive in these flat rates.

The Board believes that providing reimbursement for follow up assessments made by qualified licensed personnel could provide significant savings in health care costs through shorter rental periods and fewer emergency room visits and hospital readmissions.

ATTACHMENTS

1. Reports from FDA Meetings Held June 6 and 7, 2002 and September 12 and 13, 2002
2. Indiana University Study by Robert Czachowski, PhD, *Study Finds Respiratory Care Instruction Very Limited in Nursing Schools*
3. California Laws and Regulations Governing Home Medical Device Retail Facilities
4. California Laws and Regulations Governing Home Health Agencies
5. Handling of Oxygen and Medical Gas Mix-Ups Warnings
6. Manufacturer and User Facility Device Experience Database Reports
7. Cost-Effectiveness of Respiratory Care White Paper issued by the American Association for Respiratory Care